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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,112	02/16/2006	Gi-Ja Lee	4251-4021	8523

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EXAMINER	
D'ANGELO, MICHAEL J	

ART UNIT	PAPER NUMBER
4185	

NOTIFICATION DATE	DELIVERY MODE
01/26/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/526,112	LEE, GI-JA	
	Examiner	Art Unit	
	MICHAEL D'ANGELO	4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/28/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-3, 5, 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn et al. (US 6,438,414).

Regarding claims 1 and 2, Conn et al. discloses two hydro gels containing enzymes for creating hydrogen peroxide in reaction with glucose (column 12, lines 41-47 and claim 1), a frame with two holes (*retention layer-68,* view figure 3), a flexible circuit board on an lower part of said frame and circuit with electrodes facings the gels with terminals for connection to an instrument (*electrode assembly-60,* view figure 3), and discloses a film attached to one side of the frame (retention layer) with holes smaller than the frame (*mask-58,* column 22 lines 34-35, view figure 3), but fails to

disclose the circuit board attached to the upper part of the frame and the film attached to the lower part of the frame.

4. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the circuit board attached to the upper part of the frame and the film attached to the lower part of the frame, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Regarding claim 3, Conn et al. discloses a tray having lips or rims (i.e. wings) to support the gel discs (column 20, lines 34-38), but fails to disclose it on the frame.

5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to put the lips or wings on the frame, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70

Regarding claim 5 in respect to claims 1-3 above, Conn et al. discloses a first and second extraction electrodes (*iontophoretic electrodes -12,14)*, formed from platinum ink with carbon (claim 42), or Ag/AgCl (claim 44), a working electrode (*working electrode-16)* containing platinum and carbon (column6, lines 17-18 and claim 44), a reference electrode (*reference electrode-18)* containing Ag/AgCl (column 6, lines 19-20) and its purpose (column 10, lines 2-3), counter electrode (*counter electrode-20)* containing platinum and carbon (column 9, lines 52-62) and its purpose (column 10 lines 5-7), in addition to using platinum ink for the electrodes (column 18, lines 27-29).

Regarding claim 9, Conn et al. discloses a first extraction electrode which is of a ring shape (*iontophoretic electrode-14),* a second extraction electrode which is of a broken ring shape (*iontophoretic electrode-12),* a working electrode which is of a circular shape inside the ring shape (*working electrode-16),* as well as a reference and counter electrode (*reference electrode-18* and *counter electrode-20)* which are of half ring shape (view figure 1A), but fails to disclose that the reference and counter electrode are surrounding the outside of the ring.

6. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the reference and counter electrode are surrounding the outside of the ring, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Regarding claim 11, Conn et al. discloses an electrode assembly *(110)* consisting of terminals, electrodes, and a flexible circuit board (view figure 4, column 18, lines 15-16) cutting components (column 29, lines 40-42), and having access to the electrodes from the rear surface (via cutting the terminals) (view figure 8H).

Also with regard to claim 11, it is noted that the device of Conn, et al. appear to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Regarding claim 12, Conn et al. discloses adhering a liner to the mask (column 19 lines 66-7 and column 20 lines 1-2), spraying a material onto a substrate (i.e. circuit

board) (column 11, lines 58-63), and spraying an adhesive on the circuit board and adhering it to the frame (column 20, lines 9-13).

7. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn et al. (US 6,438,414) in view of Sanders et al. (US 4,820,720).

Regarding claim 4, Conn et al. discloses that said two holes of said frame are shaped to accommodate said get discs (view figure 3, *retention layer-68)*, but fails to disclose wherein the bottom of said gel discs are smaller sized than the upper surface.

However, Sanders et al. discloses a gel disc (*gel layer-14)* wherein one end is smaller than the other (view figure 2).

8. It would have been obvious to one of ordinary skill in the art to modify the teachings of Conn et al. to use gel discs wherein the bottom of said gel discs are smaller sized than the upper surface as taught by Sanders et al. Doing so would reduce the amount of gel needed, therefor lowering the cost of production.

Regarding claim 5 in respect to claim 4, Conn et al. discloses a first and second extraction electrodes (*iontophoretic electrodes -12,14)*, formed from platinum ink with carbon (claim 42), or Ag/AgCl (claim 44), a working electrode (*working electrode-16)* containing platinum and carbon (column6, lines 17-18 and claim 44), a reference electrode (*reference electrode-18)* containing Ag/AgCl (column 6, lines 19-20) and its purpose (column 10, lines 2-3), counter electrode (*counter electrode-20)* containing platinum and carbon (column 9, lines 52-62) and its purpose (column 10 lines 5-7), in addition to using platinum ink for the electrodes (column 18, lines 27-29).

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Conn et al. (US 6,438,414) in view of Lee et al. (US 6,506,228).

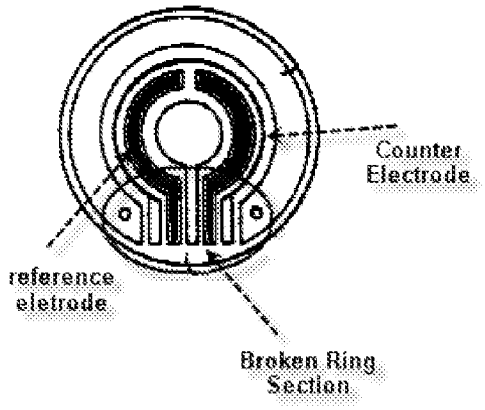
Regarding claim 6, Conn et al discloses using platinum and carbon (column 9, lines 52-62), but fails to disclose a weight ratio of 95:5.

However, Lee et al. discloses a weight ratio covering 95:5 of platinum to carbon (column 3, lines 17-19).

10. It would have been obvious to one of ordinary skill in the art to modify the teachings of Conn et al. to use a weight ratio of 95:5 as taught by Lee et al. Doing so would provide a highly conductive material which would increase electron flow through the electrodes.

11. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn et al. (US 6,438,414) in view of Kihira et al. (US 6,336,753).

Regarding claims 7 and 8, Conn et al. discloses a first electrode with a ring shape (*iontophoretic electrode-59,* view figure 3), second extraction electrode in a broken ring shape facing the gels (*bimodal electrode-630,* view figures 3 and 6), a working electrode that is circular inside the broken ring (*working electrode-631,* view figure 6), a reference and counter electrode (*reference electrode* and counter electrode, column 10, lines 18-24) that are located within the break region (view figure below) but fails to disclose that the reference electrode and counter anchor are either in series or parallel.



However, Kihira et al. discloses the concept that electrodes (i.e. reference and counter) can be in series or parallel (column 29, lines 17-24).

12. It would have been obvious to one of ordinary skill in the art to modify the teachings of Conn et al. to have the reference electrode and counter electrode in series or parallel as taught by Kihira et al. Doing so would ensure the electrodes are sufficiently connected to the circuit assembly so accurate sensing can occur.

13. Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn et al. (US 6,438,414) in view of Owens et al. (US 5,837,630).

Regarding claims 10 and 14, Conn et al. fails to disclose using voltammetry or dipping the electrodes in sulfuric acid.

However Owens et al. discloses using a 4.5M sulfuric acid solution and using cyclic voltammetry at a voltage of 1.0V (column 7, lines 54-58).

14. It would have been obvious to one of ordinary skill in the art to modify the teachings of Conn et al. to have a method of treating the electrodes using a 4.5M sulfuric acid solution and using cyclic voltammetry at a voltage of 1.0V. Doing so would ensure the electrodes can withstand voltages necessary to carry out glucose sensing.

15. Claims 13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn et al. (US 6,438,414) in view of Murata et al. (US 5,493,074).

Regarding claims 13 and 15, Conn et al. discloses that the hydro gels are put in the holes of the frame (view figure 3), copper wire as the circuits (column 9, lines 57-60) on a flexible board (column 18 lines 15-17),using a mask with an electrode pattern (column 27, lines 21-27) spraying ink on the board to make the circuit pattern (column 11, lines 56-63), repeating the steps for each material (column 27, lines 21-26), curing the film with ink for a time (column 27, lines 26-29), spraying an adhesive on the film expect for the electrodes and adhering the film to the frame containing the gel discs(column 27, lines 39-46, view figure 3), but fails to disclose a curing time.

However, Murata et al. discloses a curing/heating time of 3 hours (column 8, lines 50-54).

16. It would have been obvious to one of ordinary skill in the art to modify the teachings of Conn et al. to use a curing time of 3 hours as taught by Murata et al. Doing so would ensure the ink has dried enough so as to be cut and connected to the circuit board in a satisfactory manner.

Regarding claim 16, Conn et al. discloses cutting the border of the assembly (column 27, lines 46-49), but fails to disclose cutting the film corresponding to the terminals off

17. It is very inherent that the film is cut corresponding to said terminals since this must happen to ensure the terminals have exposed regions to be connected to the circuitry.

Regarding claim 17, Conn et al. discloses a film *mask-58* attached to one side of the frame *retention layer-68* with holes smaller than the frame (column 22 lines 33-35, view figure 3) on the opposite side of the circuit board *electrode assembly-60*.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Refer to US form 892-Notice of References Cited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL D'ANGELO whose telephone number is (571) 270-7112. The examiner can normally be reached on Monday-friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 418

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